

II. RESPONSE TO OFFICE ACTION

A. State of the Claims

Claims 53-58, 60-62, 68-80, 97-102, 109, 112-114, 123, and 137-143 were pending prior to the instant Office Action. However, claims 53-58, 60-62, and 68-80 have been withdrawn from consideration as being drawn to a non-elected invention. Therefore, claims 97-102, 109, 112-114, 123, and 137-156 were the subject of the instant Office Action.

Claims 97, 109, 137, and 144 have been amended not in response to any rejection but to clarify the invention. Support for the amendment is found either in the previously filed claims or in the specification at least on page 2, line 27; page 13, lines 34-35. Therefore, claims 97-102, 109, 112-114, 123, 137-156 are presently pending.

B. Claims 97-102, 109, 112-114, 123, and 137-156 Are Adequately Described

The Action rejects claims 97-102, 109, 112-114, 123, and 137-156 as lacking an adequate written description because these method claims recite using a polypeptide encoded by a nucleic acid comprising at least 30, 40, 50, 75, 100 or all contiguous bases of SEQ ID NO:11 yet “SEQ ID NO:11 encodes a partial receptor sequence and nowhere in the specification do Applicants disclose that they were in possession of the sequence of the entire opioid receptor encoded by a polynucleotide greater than SEQ ID NO:11.” Action at page 3. It asserts that the present claims are “reach through” claims and that “Applicants should not be entitled to claims reading on the full-length opioid receptor when they were not in possession of it at the time of the present invention.” *Id.* Applicants respectfully traverse this rejection.

The essence of this rejection has been boiled down in the most recent Action to whether Applicants are required to disclose the full-length sequence to satisfy the written description requirement. To the extent that the Examiner is relying upon other arguments for this rejection,

such as an issue regarding a relationship between structure and function, Applicants refer to previous Responses to Office Action, which are incorporated by reference.

There is no caselaw requiring that **one particular** embodiment—the full length sequence—be disclosed to fulfill the written description requirement. A review of the caselaw indicates that there is no legal support for the PTO’s position that only the full-length sequence can provide an adequate written description of the invention being claimed in this case.

“The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required ‘to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.’” *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003) (citing *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). An accepted standard for the written description requirement is: “Although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented **what is claimed.**” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-1563 (Fed. Cir. 1991) (emphasis added). Written description is met if “the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Lampi*, 228 F.3d at 1378. Again, Applicants emphasize that for purposes of the written description inquiry, the invention is whatever is **actually claimed.** *Vas-Cath*, 935 F.2d at 1563-1564. An inventor is “in possession” of an invention if the patent uses “such descriptive means as words, structures, figures, diagrams, formulas, *etc.*, that fully set forth the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). As discussed in earlier responses, by providing the sequence of SEQ ID NO:11 and the encoded polypeptide

(SEQ ID NO:12), Applicants have indicated they were in possession of SEQ ID NO:11, which is precisely what the claims recite.

Additionally, some of the claims recite portions of SEQ ID NO:11, such as 30 or 50 contiguous bases of SEQ ID NO:11. The number of species described simply by disclosing the 900 or so coding bases of SEQ ID NO:11 is enormous, and the Examiner has not disputed that thousands of species within the scope of the claims are described in Applicants' specification because SEQ ID NO:11 is provided. "A specification may, within the meaning of 35 U.S.C. §112 para. 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988). Furthermore, there is simply no legal precedent or other principle of patent law that an applicant provide one specific species in order to satisfy the written description requirement when the claims do not recite that specific species.

The Examiner is incorrect to qualify Applicants' claims as "reach-through" claims. If the Examiner is correct, then any claim reciting a nucleic acid sequence with the term "comprising" is a "reach through" claim because that sequence could be attached to any novel sequence. A "reach through claim" is identified in the PTO's own documents as "claims to future inventions based on currently disclosed inventions. Examples are "claims directed to candidate compounds that might be identified using basic screening methods and to downstream uses of such candidate compounds." See "Comparative study of 'reach-through claims'" at <http://www.uspto.gov/web/patents/biochempharm/documents/reachclaims.pps>. The Federal Circuit recently had the opportunity to evaluate this prototypical reach-through claim in *University of Rochester v. GD Searle & Co.*, 69 U.S.P.Q. 2d 1886 (Fed. Cir. 2004). In *Rochester*, one such claim recited, "A method for selectively inhibiting PGHS-2 activity in a human host, comprising

administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a host in need of said treatment.” *Id.* The patentee disclosed a method of identifying such compounds using the PGHS-2 polypeptide of the invention. However, this is a “reach-through” claim because the invention does not identify *any* compound that inhibits the PGHS-2 gene product—the “non-steroidal compound.” Contrary to this claim, which requires that some such compound be described, the screening claims in the present case can be practiced with or without the full-length sequence. It can be practiced with what is described in the specification and recited in the claims. Again, the application describes SEQ ID NO:11 and recites SEQ ID NO:11 in the claims. The present case does not contain what are considered to be “reach-through claims.”

Moreover, to satisfy the written description requirement, “an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Cordis*, 339 F.3d at 1365 (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)). Using the full-length sequence in the screening method of the invention is simply one future embodiment, which is not required in order to achieve the utility of the invention. Consequently, it is of no matter that the full-length human cDNA sequence for a kappa opioid receptor encompasses SEQ ID NO:11. The claims recite SEQ ID NO:11 and Applicants describe the sequence of SEQ ID NO:11. Therefore, Applicants are entitled to patent protection for method claims that involve SEQ ID NO:11, which has already been found to be novel, nonobvious, and useful by the PTO.

Accordingly, Applicants respectfully request this rejection be withdrawn.

C. Claims 97-102, 109, 112-114, 123, and 137-156 Are Enabled

The Action rejects claims 97-102, 109, 112-114, 123, and 137-156 as lacking enablement for reasons similar to the rationale for the written description rejection. The Action contends that the present claims are “reach through” claims. It also argues that “the claims read on the full-length protein comprising more than the bases of SEQ ID NO:11” and that “nowhere in the specification do Applicants disclose that they have enabled the use of the entire opioid receptor encoded by a polynucleotide greater than SEQ ID NO:11.” Action at page 4-5. Applicants respectfully traverse this rejection.

As stated above and in previous responses (which are incorporated by reference herein), Applicants have enabled the **claimed** invention. The MPEP states, “The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the **claim(s)** of the particular application or patent.” MPEP §2164 (emphasis added). Again, the claims recite SEQ ID NO:11 and they do not recite a “full-length kappa opioid receptor.”

In this case, the specification enables a person to make and use the claimed invention whether or not the full-sequence of the human kappa opioid receptor sequence is provided because the specification teaches how to make and use SEQ ID NO:11. Applicants point out that the pending independent claims are different, though the Action does not identify any other reason for the rejection except that the full-length sequence is not provided.

Moreover, Applicants also note that the specification provides the full-length nucleic acid and polypeptide sequences for the mouse kappa opioid receptor, which is shown aligned with the human sequence (SEQ ID NO:12) in FIG. 4a and 4b. Given the level of homology between the

mouse sequence and the human sequence, no doubt a person of ordinary skill in the art could use the mouse polypeptide sequence to devise additional nucleic acid sequences to encode the first 86 amino acids to employ in conjunction with SEQ ID NO:11. A person of ordinary skill in the art would know which nucleic acid sequences correspond to which amino acids using a codon chart readily available in any molecular biology textbook at the time the application was filed. Consequently, while the screening claims are enabled for polypeptides encoded by all or part of SEQ ID NO:11, the application is also enabled for making a full-length chimeric polypeptide.

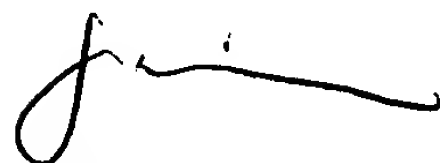
The bottom line is that other than asserting that the full-length sequence to practice the claimed invention without undue experimentation, the Examiner does not offer any other rationale for the enablement rejection. There is no evidence or argument that a person could not make and use the **claimed** invention without the full-length sequence. Accordingly, this rejection should be withdrawn.

Conclusion

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3081 is requested.

Respectfully submitted,



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